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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,451	09/21/2001	Marc O. Schurr	06530.0276-00000	2507
7590 11/09/2004 Finnegan, Henderson, Farabow Garrett & Dunner, L.L.P. 1300 I Street N.W. Washington, DC 20005-3315			EXAMINER PANTUCK, BRADFORD C	
			ART UNIT 3731	PAPER NUMBER

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/957,451

**Applicant(s)**

SCHURR ET AL.

**Examiner**

Bradford C Pantuck

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 120-167 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 120-167 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 5, 7, 120-122, 130-132, 134-136, 143-145, 147-152, 155, and 157 are rejected under 35 U.S.C. 102(b) as being anticipated by MacNeill 4,346,869. Regarding claims 1-3, 120-122, 135, and 136 MacNeill discloses a tube clamp containing: a first arm 12, and a second arm 14 that is disposed opposite to the first arm and having an end connected to an end of the first arm to define an opening. The arms are capable of securing tissue between the arms. The anchoring portion is element 32.
2. Regarding claims 5, 131, 132, 144, 145, 154, and 155, element 50 is the gripping tab.
3. Regarding claims 7, 134, 147, and 157, the first and second arms substantially form a U-shape.
4. Regarding claims 130, 143, and 153, the arm 14, contains a portion that tapers, curving away from the gap.
5. Regarding claims 148 and 149, the projection is element 46.
6. Regarding claim 150, the projection includes a barb.
7. Regarding claim 151, element 52 is the second projection.

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8. Regarding claim 152, the first and second projections are located opposite one another.
9. Claims 1, 6, 120, and 133 are rejected under 35 U.S.C. 102(b) as being anticipated by, Klieman et al. (Klieman) US 4,188,953. Klieman discloses a clip with two arms that define a gap therebetween. The clip may be made of bioabsorbable material [Column 3, lines 6-12].
10. Claims 120, 123-127, 135-140, 146, 148, and 156 rejected under 35 U.S.C. 102(b) as being anticipated by Jewusiak US 4,424,810.
11. Regarding claims 120, 135, 136, 146, 148, and 156, Jewusiak discloses a two-armed clip that has a projection in the gap between the arms. The clip is absorbable. The projection is element 15. Element 15 can be alternatively interpreted as the anchoring portion.
12. Regarding claims 123, 125, 126, 127, 137-140, the anchoring portion has two projections 15 & 25 and the projections are located opposite each other.
13. Regarding claim: 124 and 138, the projection includes a portion in the shape of a barb. Element 15 is in the shape of a barb.
14. Claims 1, 4, 120, 121, 128, 129, 135, 141, and 142 are rejected under 35 U.S.C. 102(b) as being anticipated by Cerwin et al. (Cerwin) US 4,449,531. Cerwin discloses a clip with an anchoring portion and a fixation hole. The anchoring portion has a pin [Fig. 7].

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15. Claims 1, 120, 135, 148, 149, and 158-167 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,766,189 to Matsuno. Regarding Claims 1, 120, 135, 148, 158, 159, 162, Matsuno discloses a clip (2) having two arms (2A, 2B), a bridge (2d) [see Fig. 1B], and a structure (2f) on each arm, which prevents the clip from sliding laterally (a direction perpendicular to the longitudinal axis of the clip) after being applied to tissue [Column 6, lines 36-40]. The clip is applied internally in the body [Column 1, lines 6-7] and is capable of being inserted through the esophagus to be applied to the fundus.
16. Regarding Claims 160, 161, and 163 structure (2f) includes a plurality of “protrusions,” which will each protrude into the tissue and prevent rotation. They will prevent rotation in two ways: first, by gouging into the tissue at multiple places, the clip will become stuck in the tissue; second, because there are two rows of “protrusions” (2f) on each arm [see Fig. 4] the protrusions will balance any force applied about the longitudinal axis, and prevent rotation.
17. Regarding claims 164-167, Matsuno’s clip is permanently implantable [Column 1, lines 5-14].

### *Conclusion*

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,207,692 A to Kraus et al.

U.S. Patent No. 4,889,119 to Jamiolkowski et al.

U.S. Patent No. 4,402,445 to Green

U.S. Patent No. 4,835,824 to Durham et al.

U.S. Patent No. 5,022,126 to Davis

***Response to Arguments***

19. Applicant's arguments, see "REMARKS" pages 1 and 2, filed September 10, 2004, with respect to the rejection under 35 U.S.C. 112 and the new matter objection have been fully considered and are persuasive. The rejection of claims 158-163 under 35 U.S.C. 112 has been withdrawn.
20. Applicant's arguments filed with regards to the rejection under 35 U.S.C. 102(b) (MacNeil, Klieman, Jewusiak, and Cerwin) have been fully considered but they are not persuasive. Applicant argues that MacNeil, Jewusiak, and Cerwin fail to disclose securing a fold of tissue ["REMARKS", page 14, first paragraph] and therefore do not anticipate the claimed invention. Examiner contends that each of the prior art clips have all of the physical structure of the claimed clip, and *are capable of clamping body tissue*.

Regarding clamping "in substantially the same direction as the fold of tissue", Examiner contends that the prior art clips are each capable of this function. A fold of tissue has many "directions"—in the plane of the fold and outside the plane of the fold. For example, Jewusiak's clip is shown clipping "in the direction of a fold of tissue in Fig. 2. However, this same clip can be rotated to clamp the vessel (or other folds/sections of tissue) in many different ways.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP  
BCP

November 5, 2004

  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

11/8/04